DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 9, 2014

Cook, Inc.
C/O David Lehr
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47402

Re: K132592
Trade/Device Name: Flexor® Radial Hydrophilic Introducer Access Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 3, 2014
Received: September 4, 2014

Dear Mr. Lehr,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132592

Device Name
Flexor® Radial Hydrophilic Introducer Access Set

Indications for Use *(Describe)*
The Flexor® Radial Hydrophilic Introducer Access Set is intended to introduce diagnostic and interventional devices in radial artery access procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Flexor® Radial Hydrophilic Introducer Access Set Traditional 510(k)
510(k) Summary
21 CFR §807.92

Submitter Information:

Applicant:	Cook Incorporated
Address:	750 Daniels Way Bloomington, IN 47404
Contact:	David Lehr, RAC
Email:	david.lehr@cookmedical.com
Contact Phone Number:	812-335-3575 ext. 102309
Contact Fax Number:	812-332-0281

Date Prepared:	07 October 2014

Device Information:

Trade Name:	Flexor® Radial Hydrophilic Introducer Access Set
Common Name:	Introducer Set
Classification Name:	Catheter Introducer DYB (21 CFR §870.1340)

Predicate Devices:

The Flexor® Radial Hydrophilic Introducer Access Set is substantially equivalent to the following devices: the Terumo Glidesheath Slender (K122980), the Pinnacle ROII Introducer Sheath (K082847), and the Greatbatch Medical RadialSource Transradial Access Kit (K110051).

Comparison to Predicate:

It has been demonstrated that the Flexor® Radial Hydrophilic Introducer Access Set is comparable to the predicate devices in terms of intended use, duration of use, principles of operation, technological characteristics, insertion method, and anatomical location.

Cook Incorporated
Flexor® Radial Hydrophilic Introducer Access Set Traditional 510(k)
07 October 2014

Device Description:

The Flexor® Radial Hydrophilic Introducer Access Set is comprised of an introducer sheath, a dilator, a wire guide, and an access needle.

Intended Use:

The Flexor® Radial Hydrophilic Introducer Access Set is intended to introduce diagnostic and interventional devices in radial artery access procedures.

Test Data:

The proposed Flexor® Radial Hydrophilic Introducer Access Set was subjected to applicable testing to ensure reliable design and performance under the testing parameters. The following tests were conducted to ensure reliable design and performance:

- Dilator and introducer sheath tensile testing – Testing verified that, under proper clinical use of the dilator and introducer sheath, the peak load values shall be in accordance with the applicable values of BS EN ISO 11070:1999. The predetermined acceptance criteria were met.
- Connecting tube to check-flo tensile testing – Testing verified that, under proper clinical use of the device, the connection between the valve body and the connecting tube will meet the predetermined acceptance criteria.
- Needle tensile testing – Testing verified that, under proper clinical use of the needle, the peak load values shall be in accordance with the applicable values of BS EN ISO 11070: 1999. The predetermined acceptance criteria were met.
- Needle tubing testing – Testing verified that, under proper clinical use of the needle, the tubing will resist breakage in accordance with EN ISO 9626: 1995. The predetermined acceptance criteria were met.
- Check-Flo valve dislodgement testing – Testing verified that the Check-Flo valve will not be dislodged during insertion and withdrawal when utilized according to the device's intended use. The predetermined acceptance criteria were met.
- Check-Flo valve liquid leakage testing – Testing verified that the Check-Flo valve will not experience excessive leakage when utilized according to the device's intended use. The predetermined acceptance criteria were met.
- Dimensional verification – Testing verified that each component met the dimensions within tolerances of the predetermined acceptance criteria.
- Fluoroscopic visibility evaluation – Testing verified that each component was visible under fluoroscopy. The predetermined acceptance criteria were met.
- Design validation – Design was validated through simulated clinical use. The predetermined acceptance criteria were met.
- Insertion and extraction force evaluation – The insertion and extraction forces of the dilator through the check-flo valve were evaluated and characterized. The predetermined acceptance criteria were met, where appropriate.
- Dilator and introducer sheath coating slough-off – Testing verified that the hydrophilic coating met the requirements for durability. The predetermined acceptance criterion was met.

- Particulate evaluation – Particulate counts were recorded in continuous flow loop.
- Introducer lubricity testing – Lubricity of the introducer shaft was evaluated. The predetermined acceptance criterion was met.
- Coating integrity testing – Surface of device, including the hydrophilic coating, was visually examined at multiple time points.
- Wire guide testing – Testing verified all predetermined acceptance criteria were met for resistance to fracture, resistance to damage by flexing, tensile, tip deflection, torque response and torque strength as recommended in BS EN ISO 11070:1999 and in "Coronary and Cerebrovascular Guidewire Guidance," January 1995.
- Biocompatibility testing – Testing (i.e., cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogen, hemocompatibility, complement activation, partial thromboplastin time, and thromboresistance) demonstrated the device as biocompatible. In conformance with the applicable sections of ISO 10993-1:2009, the predetermined acceptance criteria were met.

In conclusion, the results of these tests provide reasonable assurance to support a determination of substantial equivalence to predicate devices.